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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,225	12/01/2003	Bruno Tocque	ST95050-US/A	9762

29693 7590 01/10/2006
WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/724,225

Applicant(s)

TOCQUE ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/029,327.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1,3-6 and 8-10 are presently pending.

Response to Arguments

Claim Rejections - 35 USC § 112

3. Claims 1,3-6 and 8-10 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the prior Office action, and those reasons set forth below in response to Applicant's arguments.
4. Applicant's arguments filed 10-24-05 have been fully considered but they are not persuasive. Applicants traversed the rejection of claim 1 by way of amending the claim to recite a method for determining the cell growth activity of a cell, and concluding that the claim as amended does not omit essential steps.

Contrary to Applicant's assertions, claim 1 as amended recites in the last several line of the claim "and measuring the growth of the cell, compared to a control transforming." This phrase is vague and indefinite since the relationship of the term "transforming" and the remainder of the phrase is uncertain.

In regards to claim 6, and those claims dependent therefrom, Applicants traverse by way of amending the claim to remove the phrase "protein-protein" from the first line of the claim. Applicant's amendment does not remedy the clarity of the claim. In the

prior Office Action it was stated that "there is no indication that the binding recited in the last step of this method represents binding of the cell cycle regulatory protein with mdm2, the generic recitation of the term 'binding' may encompass binding of any cellular component with mdm2, not just binding of proteins to mdm2." Applicants have not addressed this point. The claim, as amended, is now directed to "a method of detecting interaction with a mdm2 protein," wherein the method comprises introducing a nucleic acid encoding amino acids 1-134 of the mdm2 protein, and a nucleic acid encoding a cell cycle regulatory protein into the same cell, however according to Applicant's response, "amended claim 6 does not refer to 'protein-protein' interaction," and that one of ordinary skill in the art would also understand that introducing another protein into the cell may alter the oncogenic character and can thus determine interaction with the known effects of the mdm2 protein of 1-134 amino acids of SEQ ID NO: 1. Applicant's response is unclear, since the features upon which Applicants are relying upon, namely an alteration in oncogenic character, is not recited in the claim. Moreover, the last line of the claim recites "a change in cell growth or proliferation is indicative of binding to mdm2," however there is no indication or means of confirming that actual binding is taking place, and there is no indication as to what is binding mdm2.

Claim Rejections - 35 USC § 103

5. Claims 1, 3-6 and 8-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (WO 93/20238 A2), for the reasons of record.

Applicant's arguments filed 10-24-05 have been fully considered but they are not persuasive. Applicants traversed the rejection of claim 1 by way of amending the claim to recite the amino acids 1-134 of SEQ ID NO: 1, and according to Applicants the Burrell document refers to regions of the mdm2 sequence at the C-term end, and thus does not teach or suggest applicant's amendment.

Contrary to Applicant's assertions, as stated in the prior Office Action, the sequence of amino acid MDM2 as set forth in amino acids 1 to 134 of SEQ ID NO: 1 is set forth in Burrell et al. at Figures 1A-1C. In particular, Burrell et al. teach the determination of MDM2 and p53 domains of interaction, see Figures 5 and 6, in particular Figure 6B which demonstrates that nucleic acid encoding the first 135 codons of MDM2 was capable of p53 dependent activation. Therefore, as stated in the prior Office Action, contrary to Applicant's assertions, and the lack of sufficient evidence to the contrary, although Burrell et al. does not teach the exact method steps recited in the instant claims, it is clear that one of ordinary skill in the art at the time of the instant application, seeking potential therapeutics for treating MDM2 associated neoplastic cell growths, would have been motivated to modify the teachings of Burrell et al. to design the methods recited in the instant claims. One of ordinary skill in the art at the time of the instant invention would have been motivated to make this modification since Burrell et al. clearly teach that potential therapeutic molecules can be identified by identifying molecules which inhibit the binding of MDM2 to p53, and further determining whether this inhibition alleviates p53 sequestration (see page 11, lines 1-2), with the expectation that p53 regulated cell growth control would be restored (see page 11, 3rd paragraph).

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Moreover, one of ordinary skill in the art seeking alternative means for isolating inhibitors of MDM2 function would have been motivated to practice the methods of the instant invention in saos-2 cell, since Burrell et al. specifically teach that MDM2 is amplified in osteosarcomas (see page 19, 4th paragraph), and since saos-2 cells are osteosarcoma cells, it would have been obvious at the time of the invention to substitute one functionally equivalent cell line with another, with the expectation that MDM2 would also be amplified in saos-2 cells as the prior art cells.

Therefore, the invention as a whole would have been *prima facie* obvious over Burrell et al.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

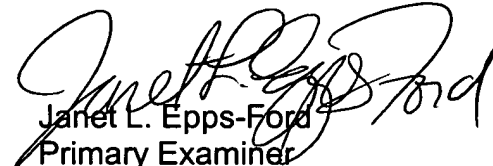
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Janet L. Epps-Ford
Primary Examiner
Art Unit 1633

JLE